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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,620	12/30/2003	Xiaobing Wu	04577/0200726-US0	6175

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EXAMINER	
SAJJADI, FEREYDOUN GHOTB	
ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/750,620	WU ET AL.	
	Examiner	Art Unit	
	Fereydoun G. Sajjadi	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, drawn to a recombinant plasmid AAV vector, comprising an HO-1 gene; a cell strain containing said vector; an AAV virus produced from said vector; and a process of producing recombinant AAV virus containing the HO-1 gene by transfecting a host cell with said vector or said AAV virus, and a method of mediating HO-1 gene expression, comprising administering an effective amount of a recombinant AAV vector classifiable in class 514, subclass 44 and class 424, subclass 93.1.

II. Claims 12-13, drawn to a method of preventing chronic post-transplant rejection, comprising administering an effective amount of recombinant AAV/HO-1 virus, classifiable in class 424, subclass 93.2.

III. Claim 15-17, drawn to a method of preventing chronic post-transplant allograft rejection, comprising recombinant AAV-mediated HO-1 gene expression in grafts, classifiable in class 424, subclass 93.2.

IV(i). Claim 17, drawn to a method of preventing chronic post-transplant allograft rejection, comprising a gene delivery method for HO-1 gene expression in grafts, together with a substance, classifiable in class 514, subclass 44.

IV(ii). Claim 17, drawn to a method of preventing chronic post-transplant allograft rejection, comprising a protein delivery method for HO-1 expression in grafts, classifiable in class 514, subclass 44.

IV(iii). Claim 17, drawn to a method of preventing chronic post-transplant allograft rejection, comprising a protein delivery method for HO-1 expression in grafts, together with a substance, classifiable in class 514, subclass 44.

IV(iv). Claim 17, drawn to a method of preventing chronic post-transplant allograft rejection, comprising using a substance for the induction of stable HO-1 expression, classifiable in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

The invention of Group I is directed to a recombinant plasmid harboring an HO-1 gene and cells comprising the same and a method of mediating HO-1 gene expression comprising administering an effective amount of a recombinant AAV vector. The invention of Group II is directed to a method

of preventing chronic post-transplant rejection, comprising administering an effective amount of recombinant AAV/HO-1 virus. The method of Group II does not require the vector-containing cell strain of Group I, and the vectors of Group I may be used for transfer of the HO-1 gene to non-transplant tissues. Therefore, each is not required for the other. The inventions of Groups II and III are distinct, each from the other because the method of Group II claims is directed to the prevention of chronic post-transplant rejection, that may include xenografts and xenotransplants. By contrast, the preventive method of Groups III claims are limited to allografts (allogeneic, same species). Further, the inventions of Groups III do not require the particulars (such as cell strains) of Group I and vice versa. Finally, Groups IV(i)-IV(iv) are distinct each from the other, because the inventions of Groups IV are directed to different methods, comprising gene delivery together with a substance (IV(i)), protein delivery (IV(ii)), protein delivery together with a substance (IV(iii)), and a substance alone IV(iv). Because the gene and protein may be used alone or in combination with the substance, each represents a structurally distinct combination of elements. Further, the substance of invention IV(iv) does not require the particulars of inventions IV(i)-IV(iii). The delivery methods of inventions in Groups IV are also distinct from the invention of Group I, since the vectors of Group I may be used separately from the post-transplant allograft rejection paradigm.

The vectors and cell lines of Group I and the methods of gene expression and prevention of transplant rejections described in Groups II-IV have a separate status in the art, as shown by their different classifications. In the instant case, the search of the different products and methodologies together are not coextensive. The search of inventions of Groups I-IV together would therefore impose a serious search burden.

Claim 14 links inventions III and IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim 14. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no

longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions I-IV(i) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05(h)). In the instant case the mammalian cell of claim 18 (the product) may be used to express specific proteins of interest, rather than for *ex vivo* therapy of a genetic disease or cancer.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition

against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

This application contains claims directed to the following groups of patentably distinct species of the claimed invention:

Group IV – Applicant is required to choose either a method for gene delivery, or protein delivery or a substance for the induction of stable HO-1 expression, as recited in claim 17.

Applicant is required under 35 U.S.C. §121 to elect a single disclosed species for each of the groups above, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 17 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, and/or because of the patentably distinct species are listed above, it would be unduly burdensome for the examiner to search and examine all of the subject matter being sought in the presently pending claims, and thus, restriction for examination purposes as indicated is proper.

Applicant is advised that the response for this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Victor Barlow, whose telephone number is **(571) 272-0506**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fereydoun G. Sajjadi whose telephone number is **(571) 272-3311**. The examiner can normally be reached Monday through Friday, between 7:00 am-4:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on **(571) 272-0731**. The fax phone number for the organization where this application or proceeding is assigned is **(571) 273-8300**. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

For all other customer support, please call the USPTO Call Center (UCC) at **(800) 786-9199**.

Fereydoun G. Sajjadi, Ph.D.
Examiner, USPTO, AU 1633

DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER